DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 15 2011

Re: CERVARIX
Docket No.: FDA-2010-E-0332

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 7,351,533, filed by MedImmune, LLC., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for CERVARIX (Human Papillomavirus Bivalent (Types 16 & 18) Vaccine), the human biological product claimed by the patent.

The total length of the regulatory review period for CERVARIX is 4,027 days. Of this time, 3,094 days occurred during the testing phase and 933 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this biologic product became effective: October 9, 1998.

   The applicant claims September 8, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 9, 1998, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: March 29, 2007.

   FDA has verified the applicant's claim that the biologics license application (BLA) for CERVARIX (BLA 125259/0) was submitted on March 29, 2007.

3. The date the application was approved: October 16, 2009.

   FDA has verified the applicant's claim that BLA 125259/0 was approved on October 16, 2009.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Raymond J. Lillie
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